

Dean L. Engelhardt et al., Serial No.: 08/486,069 (Filed: June 7, 1995)  
Exhibit 1 [July 7, 2005 Amendment Under 37 C.F.R. §1.116]

# EXHIBIT 1

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**Substance of the April 1, 2004 Interview**

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The April 1, 2004 interview was attended by Examiner Ardin H. Marschel, Group Art Unit 1631, Eugene C. Rzucidlo, Esq. of Greenberg Traurig (New York, NY), Dr. James J. Donegan, Applicants' representative and also a senior scientist for the assignee of Serial No. 08/486,069, and Ronald C. Fedus, Esq., Applicants' attorney of record. In the Interview Summary dated April 1, 2004, it is indicated that "[w]e discussed a number of possible claim amendments to overcome the rejections of record."

As described below, a number of matters were discussed at the April 1, 2004 interview.

***Furanosyl***

Applicants' representatives and attorney urged that in contrast to the term "furanose moiety," the term "furanosyl moiety" better describes the nature of the ring element in nucleic acid structure. The Examiner seemed willing to consider, if not accept, the proposed change in the claims from "furanose moiety" to "furanosyl moiety." Applicants' attorney indicated that in their next response the claims would be amended to reflect this change to "furanosyl moiety."

***Nucleotide Analog***

The matter of nucleotide analogs was also discussed at the April 1, 2004 interview. Applicants' attorney explained that the term "nucleotide analog" is a term long recognized in the art, as evidenced by the books authored by Prof. Dr. Karl Heinz Scheit [Nucleotide Analogs: Synthesis and Biological Function, John Wiley & Sons, New York, 1980], and Dr. Arthur Kornberg [DNA Synthesis, W. H. Freeman and Company, San Francisco, CA 1974; DNA Replication, also Freeman and Company,

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1980; 1982 Supplement to DNA Replication, again, Freeman and Company].<sup>1</sup>  
Applicants' attorneys also pointed out that Kornberg's "nucleotide analogs" were defined as those molecules that could be incorporated into DNA or RNA. It was generally agreed at the April 1, 2004 interview that the term "nucleotide analog" could be recited in the claims, with additional embodiments or language directed to "base analogs," because Applicants' specification disclosed several examples of these. Applicants' attorney indicated that the claims would be amended in their next response to reflect the term "nucleotide analog," and that some dependent claims would be appropriately amended or presented to reflect the term "base analogs" and various related terms.

#### ***Indicator Molecule***

The nature of "indicator molecule" had been raised in the July 1, 2003 Office Action (pages 8-9). It is believed that this matter was briefly discussed at the April 1, 2004 interview. It is also believed that Applicants' attorneys indicated that some amendments would be effected to the claims in order to clarify the relationship between the detectable non-radioactive moieties A or Sig and the indicator molecules.

#### ***Non-Nucleotidyl***

At the April 1, 2004 interview, various pieces of prior art cited in the July 1, 2003 Office Action were discussed. Regarding the Dunn [Cell 12:23 (1977)] and Hartman [Biopolymers 20:2635 (1981)] documents, it was generally agreed that a description in the claims that the detectable non-radioactive moiety was *non-nucleotidyl* in nature, would probably overcome the prior art rejections. The Examiner did indicate, however, that a showing of support for the term "non-nucleotidyl" would be necessary. Applicants' attorneys indicated that the claims would be amended in their next response to reflect the "non-nucleotidyl" nature of

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<sup>1</sup> These books are already of record in this application.

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the detectable non-radioactive moiety. Applicants attorneys further indicated that a showing of support would be made in connection with those claim amendments.

With respect to claim 1411 in which the detection process is carried out with a non-radioactively detectable protein, it was generally agreed at the April 1, 2004 interview that the recitation of "operator sequence" in the claim would probably overcome the anticipation rejection by Kourilsky (P/N 4,581,333 and GB 2,019,408). At the April 1st interview, Applicants attorneys and representative indicated that "operator sequence" was being used in a classical sense, much as in Example XXXIV in the specification. The latter statement was made in response to the Examiner's query at the April 1, 2004 interview.

The interview then concluded.

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June 29, 2005